



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/243,102	02/02/99	MACLACHLAN	I 16303-73-2

020350 HM12/1010
TOWNSEND AND TOWNSEND AND CREW
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO CA 94111-3834

EXAMINER

ZARA, J

ART UNIT	PAPER NUMBER
----------	--------------

1635

12

DATE MAILED: 10/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/243,102

Applicant(s)

MACLACHLAN ET AL.

Examiner

Jane Zara

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 29-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

KATRINA TURNER
PATENT ANALYST

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

Art Unit: 1635

DETAILED ACTION

This Office action is in response to the communication filed July 23, 2001, Paper No. 11.

Response to Arguments**Maintained Rejections**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims ¹⁻²⁸ 1-28 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the Office action mailed January 11, 2001, Paper No. 8.

Applicant's arguments filed July 23, 2001 have been fully considered but they are not persuasive.

Applicants assert that the instant specification is enabling for the scope claimed because the instant disclosure provides examples of previously disclosed therapeutic nucleic acids as well as providing teachings concerning the preparation and properties of lipid/therapeutic nucleic acid particles which exist in the art. The example of tumor reduction effects provided by the administration of a lipid encapsulated, highly active and highly stable form of the enzyme thymidine kinase (HSV-TK), in combination with ganciclovir is not representative of the ability to treat any neoplasm comprising the distal administration of any expressible gene fully encapsulated within any lipid-nucleic acid particle. The claims are enabled for the scope drawn to treatment effects provided comprising the administration of the nucleic acid encoding HSV-TK and

Art Unit: 1635

ganciclovir, which nucleic acid is fully encapsulated in the lipid formulation (or formulations) explicitly disclosed.

Applicants further assert that the instant specification is enabling for the scope claimed, which scope comprises a method to treat any neoplasia comprising the administration of any expressible gene which is fully encapsulated in the lipid portion of any nucleic acid lipid particle, because working examples have been provided which describe the in vivo delivery and tumor reduction in mice following the administration of lipid formulated HSV-TK in combination with ganciclovir

Treatment effects are not necessarily provided by a nucleic acid merely because that nucleic acid has not been degraded by nucleases in the serum of an organism. The instant disclosure is enabling for the increased stability of fully encapsulated nucleic acids in serum which are present in lipid-nucleic acid particles comprising the formulations 1.1, 1.2, 1.3, 1.4 and 1.5, but not for the treatment of any neoplasia comprising the administration of any expressible nucleic acid encapsulated within such lipid-nucleic acid particles.

Art Unit: 1635

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. **NOTE:** If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820**. If attempts to

Art Unit: 1635

reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



SEAN MCGARRY
PRIMARY EXAMINER

JZ

October 9, 2001